REMARKS

Reconsideration of the merits of the application is respectfully requested in light of the remarks that follow.

Election/Restrictions

Applicants acknowledge that claims 16-20 have been withdrawn from consideration. Applicant also acknowledges that the Examiner has indicated that claim 21 is directed to an invention that is independent or distinct from the invention originally claimed. Although Applicant does not necessarily agree with this statement, Applicant notes that under MPEP § 821.04, if a product claim is found allowable, a process claim that either depends on or contains all of the limitations of the allowable product claim will be fully examined and rejoined.

Rejection over Schaer, U.S. Patent No. 6,251,107 under 35 USC §102

Claims 1, 2, 4, 8, and 10-13 have been rejected under 35 USC §102(e) as allegedly being anticipated by Schaer. Applicants respectfully traverse the rejection.

Claims 1-4 and 8-13 were amended in the previous response to require an electrode connector connected to a conductor and the coil electrode. The Examiner asserts that element 34 is considered to be the electrode connector since it is both coupled/connected/adhered to the coil electrode and conductor. Applicants respectfully disagree that element 34 can be considered to be an electrode connector of the pending claims.

The element that the Examiner refers to, the fluoropolymer jacket 34, is described in Schaer at column 5, lines 43-54. As stated there, the jacket 34 "covers the conducting member 33 and insulates the temperature sensor 17 from noise (e.g. RF noise) present as a result of the energy sent to the electrodes. The jacket 34 may cover at least part of the electrodes 16, as for example, the edges of the individual electrodes to prevent exposure of a sharp metallic edge of the electrode." (column 5, lines 43-50) Furthermore, the jacket is preferably formed of THV (column 5, lines 43-44). THV refers to a product made by 3M® whose full name is Dyneon™ THV Fluorothermoplastic, which is a polymer of tetrafluoroethylene, hexafluoropropylene and vinylidene fluoride.

The electrode connector, as utilized in the pending claims provides an electrical and mechanical connection for the wire coil 210. Furthermore, the electrode connector 225 may, in some alternatives of the invention provide part of the electrode surface area and electrode length.

The jacket 34 of Schaer does not and indeed could not function in this same capacity, therefore, the jacket 34 of Schaer cannot be considered to be the electrode connector, as argued by the Examiner. Therefore, Schaer does not provide all of the elements of the invention and therefore does not anticipate any of the pending claims, and particularly does not anticipate claims 1, 2, 4, 8, and 10-13. Accordingly, withdrawal of the rejection is respectfully requested.

Rejection over Speicher et al., US Patent No. 4,603,705 under 35 USC § 102 or § 103

Claims 1, 2, 4, and 11-13 have been rejected under 35 USC §102(b) as allegedly being anticipated by or alternatively under 35 USC § 103(a) as obvious over Speicher et al. Applicants respectfully traverse the rejection.

The Examiner asserts that Speicher anticipates claims 1, 2, 4, and 11-13 because the device of Speicher is capable of meeting the functional use recitations presented in the claims, and meets the claimed limitation of "about 2 mm" since his coil diameter is "about 3 mm". Applicant respectfully disagrees with the Examiner regarding both of these points, and asserts that Speicher does therefore not anticipate claims 1, 2, 4, and 11-13.

First, the Applicant disagrees that the functional use recitations are met. The Examiner asserts that the functional use recitations are met because he uses "an implantable flexible coil electrode". Applicant does not agree that such a conclusory statement is sufficient to show that the device could be used for "electrical stimulation of one or more sacral nerves of a human patient". Indeed, Applicant respectfully submits that the device of Speicher would not be flexible enough to be used within the foramen of the human sacrum because it would be too rigid which could result in irritation of the nerve itself. A more flexible lead/electrode allows movement of the lead/electrode without injuring the nerve. The Applicant does not believe that the Examiner has cited any reference to show that the opposite is the case, i.e. that the device of Speicher, which has a longer coil electrode could fit within the foramen of the human sacrum. Applicant can only assume, absent some citation, that the Examiner is taking official notice of the fact that the device of Speicher can be used for "electrical stimulation of one or more sacral

nerves of a human patient". Applicant therefore asserts that reliance on "common knowledge", as provided for in MPEP § 2144.03 is improper in this situation.

The Applicant asserts, as a preliminary matter, that this is not a proper time to take "official notice" without documentary evidence to support the conclusion because, as stated by MPEP § 2144.03 (A), the circumstances that make this reliance permissible "should be rare when an application is under final rejection". It is stated that official notice unsupported by documentary evidence should only be taken by the examiner when the facts asserted to be well-known, or to be common knowledge in the art are capable of **instant and unquestionable demonstration as being well known** (MPEP § 2144.30(A) emphasis added). An example of a situation where "official notice" would be appropriate is to assert without more that, "it is old to adjust intensity of a flame in accordance with the heat requirement". Contrary to that, it is not appropriate, based on "official notice" to assert facts constituting the state of the art, because the facts constituting the state of the art are normally subject to the possibility of rational disagreement among reasonable men. Applicant respectfully asserts that the area of sacral stimulation is certainly state of the art, and therefore devices that are or are not capable of carrying out sacral stimulation are also state of the art. Based on this argument, Applicant respectfully asserts that it is improper in this situation to take official notice that the device of Speicher can be used for "electrical stimulation of one or more sacral nerves".

Applicant also asserts, that the technical line of reasoning underlying the decision to take official notice was not clear and unmistakable, as required in this situation by MPEP § 2144.03(B). The MPEP requires that the Examiner "must provide specific factual findings predicated on sound technical and scientific reasoning to support his or her conclusion of common knowledge" (MPEP § 2144.03(B)). As a procedural matter, it is noted that the Applicant should be presented with the explicit basis on which the Examiner regards the matter as subject to official notice and be allowed to challenge the assertion in the next reply after the Office action in which the common knowledge statement was made (MPEP § 2144.03(B). Then, once the Applicant has challenged the statement, as Applicant has done herein, the Examiner must support the finding with adequate evidence (MPEP § 2144.03(C)).

In summary, it is respectfully asserted that it was not proper for the Examiner to take official notice of the fact that the device of Speicher can be used for sacral stimulation and

therefore, claims 1, 2, 4, and 11-13 are not anticipated by Speicher because it does not include all of the elements of claims 1, 2, 4, and 11-13.

Second, the Applicant does not agree that Speicher teaches a device that has a coil diameter of "about 0.5 mm to about 2.0 mm". The Examiner asserts that the coil electrode of Speicher, which is "about 3.0 mm to 4.0 mm", meets this limitation. Applicant respectfully disagrees that "about 3.0 mm to 4. 0 mm" is equal to "about 0.5 mm to about 2.0 mm". In order for prior art to anticipate a range in the claims, the claimed subject matter must be disclosed in the reference with "sufficient specificity to constitute an anticipation under the statute" (MPEP § 2131.03). What constitutes a "sufficient specificity" is fact dependent, and it is mentioned by MPEP § 2131.03 that in some cases, the Examiner must provide reasons for anticipation as well as a motivational statement regarding obviousness. Applicant respectfully asserts that the Examiner has not provided any more than a conclusory statement that "about 0.5 mm to about 2 mm" is equal to "about 3 mm", and therefore Speicher does not anticipate claims 1, 2, 4, and 11-13.

The Examiner also alternatively asserts that Speicher renders claims 1, 2, 4, and 11-13 obvious. Applicant respectfully asserts that Speicher does not render claims 1, 2, 4, and 11-13 obvious because a *prima facia* case of obviousness has not been shown. The Examiner asserts that it would have been obvious to one of skill in the art to modify the implantable lead with coil electrode taught by Speicher to a coil electrode with a diameter of about 0.5 mm to about 2.0 mm. Applicant respectfully disagrees with the Examiner regarding this statement, because Speicher taught against such a modification and such a modification could have rendered it unsatisfactory for its intended purpose.

The electrode of Speicher was developed to overcome deficiencies of the prior art, such as "an effective multiple electrode unitary intravascular catheter capable of sensing heart abnormality and delivering either defibrillating energy or pacing energy in response to the abnormality for restoring normal heart function" (Speicher, column 3, lines 13-18). It was also noted in Speicher that "none of the prior art devices noted above is capable of delivering a high-energy discharge through a single catheter and immediately being able to effectively sense the heart's electrical activity through the same catheter" (Speicher, column 3, lines 19-23). This, according to Speicher was the intended purpose of the device disclosed therein.

The electrode of Speicher is able to deliver the high-energy discharge necessary for defibrillation because of the coil electrode, or the spring **23** as it is referred to in Speicher. As stated in Speicher, the "close-wound spring provides a continuous electrically conductive surface which maintains its flexibility while still lowering the impedance of the electrode and thus permitting more current to be delivered" (Speicher, column 5, lines 44-48). The surface area of the spring **23**, being about 30 to 50 mm^2 (Speicher, column 5, lines 47-48) is also important to deliver the type of discharge necessary for defibrillation.

Given the purpose of the electrode of Speicher, as evidenced by the Background of the Invention, one of skill in the art would not have been motivated to decrease the diameter of the coil electrode because that would decrease the amount of energy that could be discharged through the coil. Therefore, the disclosure and purpose of the device of Speicher would teach away from such a modification. Such a modification could in fact render the electrode of Speicher less satisfactory, or entirely unsatisfactory for its intended purpose. As stated in MPEP § 2143.01, "the proposed modification cannot render the prior art unsatisfactory for its intended purpose".

Contrary to the invention of Speicher, it is desirable that the electrode of the instant claims be flexible so that it does not irritate the tissue and/or nerve that it is located within or near. Furthermore, there is a desire that the lead create a maximum neurostimulation field in order to excite the adjacent nerve, i.e. a low energy density. This is contrary to the intended purpose of Speicher, where maximum current density is the focus. Maximum current density, and maximum field size are opposing purposes when the size of the electrode is the factor to be considered. Therefore, the device of Speicher does not render claims 1, 2, 4, and 11-13 obvious, because there is not motivation to modify the teachings of Speicher to result in the subject matter of claims 1, 2, 4, and 11-13.

In light of the remarks offered above, Applicant respectfully requests that the Examiner withdraw this rejection.

Claims 3 and 8-10 have been rejected under 35 USC § 103(a) as obvious over Speicher et al. Applicants respectfully traverse the rejection. Applicant reiterates the comments offered above and submits that the independent claim, claim number 1, which claims 3, and 8-10 are dependent on is not obvious, and therefore neither are claims dependent thereon. In light of the

remarks offered above, Applicant respectfully requests that the Examiner withdraw this rejection.

In view of the foregoing remarks, it is believed that the application is now in condition for allowance and notice of this, in the form of a notice of allowance is respectfully requested.

Respectfully submitted,

Date: January 19, 2005

Anna M. Nelson
Registration No. 48,953
MEDTRONIC, INC.
710 Medtronic Parkway NE, M.S.: LC340
Minneapolis, Minnesota 55432-5604
Telephone: (763) 505-0405
Facsimile: (763) 505-0411
CUSTOMER NO.: 27581